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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,635	05/18/2000	OLIVIER BALLEVRE	P00.0164	7617

7590 01/02/2002

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EXAMINER
LUKTON, DAVID

ART UNIT	PAPER NUMBER
1653	16

DATE MAILED: 01/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/508,635	Ballevre
Examiner	**Art Unit**
David Lukton	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on Feb 16, 2001

2a) [ ] This action is **FINAL.** 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) 11-29 is/are pending in the applica

4a) Of the above, claim(s) 14 is/are withdrawn from considera

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) 11-13 and 15-29 is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirem

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are objected to by the Examiner.

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____.
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) [X] Notice of References Cited (PTO-892)
16) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) [ ] Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
18) [ ] Interview Summary (PTO-413) Paper No(s) _____
19) [ ] Notice of Informal Patent Application (PTO-152)
20) [ ] Other

Pursuant to the directives of paper No. 13 (filed 2/16/01), claims 1-10 have been cancelled, and claims 11-29 added.

As indicated in the Office action mailed 5/10/01, Robert Barrett verbally agreed to the following restriction requirement, and further, elected group III:

III. Claims 11-13, 15-29, drawn to a method of promoting the growth or recovery of a specific organ in a mammal.

IV. Claim 14, drawn to a method of increasing protein synthesis.

Affirmation of this election must be made by applicant in responding to this office action. Claim 14 is withdrawn from further consideration by the Examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. In addition to the foregoing, the previous species election (protein hydrolyzates) remains in force.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-22 and 27-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one

skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The issue addressed is that of accelerating the repair of a damaged organ. Applicants have shown that one can select a level of protein/amino acid which is at or below the lower limit of that required for optimal nutrition, and that if one then raises the level of protein/amino acid which is administered, increase in the weight of one or more organs can result. However, this does not mean that wound healing will be increased, or that cirrhosis of the liver can be treated, or that ulcers can be treated or that inflammatory bowel disease can be treated, or that cancer (of e.g., liver or stomach) can be treated. All of these would be encompassed. The reality is that for most people who are already receiving adequate nourishment, increasing the intake of meat will not heal any wounds, or cause remission of cancer or eradicate symptoms of inflammatory bowel disease. Moreover, if the kidney is the organ that is damaged, administration of large quantities of protein could make matters worse. Increase in weight of an organ does not translate into increased wound healing.

*

Claims 11-22 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 16 recites the phrase "at least about", thus rendering the claim indefinite as to the lower limit of the degree of hydrolysis.

- Claim 11 recites the term "recovery". What does this mean? Is it necessary that damage to the tissue occurs? If so, this should be made clear.

*

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

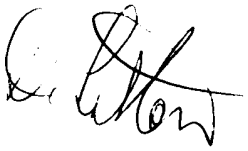
Claims 11, 13, 17, 19, 21, 23, 25, 26, 27, 28 rejected under 35 U.S.C. §103 as being unpatentable over Ballard (USP 5,679,771).

Ballard discloses that IGF-1 increases the weight of the gut (including intestines and jejunum) and improves gut function, and accelerates healing of damaged gut tissue.

The issue here is that which is meant by the term "dietary protein". There are four

different situations for the "mammal" in question: (a) a carnivorous animal living in the wild, (b) an animal who relies solely on humans for food, (c) a human living in a civilized society, and (d) a human living in an "uncivilized" society. With regard to the first of these (a carnivorous animal living in the wild), clearly there are many animals that eat all of the flesh of other animals, and so one can expect that IGF-1 will be consumed. With regard to the second of these, a veterinarian is likely to administer the IGF-1 by mixing it with food; as such, the IGF-1 becomes a "dietary peptide". As for humans living in a civilized society, it is conceivable that a person would want to mix the IGF-1 with food, and in so doing, the IGF-1 becomes a "dietary peptide". The last category would include humans on the African continent living as they did thousands of years ago. Some of these persons eat raw meat, and as such would ingest the IGF-1 produced by the animals which they have killed.

Thus, the claims are rendered obvious.



DAVID LUKTON
PATENT EXAMINER
GROUP 1800

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton [phone number (703)308-3213].

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.